THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

Shire Development LLC, Shire Pharmaceutical Development Inc., Cosmo Technologies Limited, and Nogra Pharma Limited.	:	
***Plaintiffs*,**	:	**1:15-cv-02865 (RBK/JS)**
v.	:	**OPINION**
Amneal **Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals Co. (1) PVT. LTD., and Amneal Life Sciences PVT. LTD.**	:	
***Defendants*.**	:	

KUGLER, United States District Judge:

This matter comes before the Court on the motion [ECF Doc. 373] by defendants' (collectively "Amneal" or "defendants"), seeking a declaration this case is "exceptional" under 35 U.S.C. § 285[1] and an award of defendant's attorneys' fees after 31 August 2017, the date plaintiffs (collectively "Shire" or "plaintiffs") served their expert reports.

For the reasons discussed below, defendants' motion is **DENIED**. An order accompanies.

1.0 Relevant Facts and Procedural History

On 22 April 2015, plaintiff Shire filed a patent infringement suit against defendants Amneal ("the Amneal ANDA suit" or "this suit") after Amneal sought approval in the form of an Abbreviated New Drug Application ("ANDA") from the Food and Drug Administration ["FDA"] for a generic form of the drug Lialda®, covered by U.S. Patent Number 6,773,720 (" '720 patent").[2] Claim 1 of the '720 patent recites a controlled-release oral pharmaceutical composition comprising the active ingredient 5-amino-salicylic acid and having an inner lipophilic matrix and an outer hydrophilic matrix wherein the active ingredient is dispersed in both the lipophilic matrix and hydrophilic matrix. The lipophilic matrix consists of substances

[1] 35 U.S.C.§285 reads in its entirety: T*he court in exceptional cases may award reasonable attorney fees to the prevailing party.*
[2] According to the Orange Book, the '720 patent expires 8 Jun 2020.

derived from fatty acids or cholesterol; the hydrophilic matrix consists of water soluble substances.

From 2012 through November 2015, in response to other ANDA applications before the FDA, Shire filed similar patent infringement cases against these ANDA applicants: Zydus, Osmotica, Watson (now Teva), Mylan, and Lupin (ECF Doc. No. 380-3) ["the other ANDA cases"].

For plaintiff, neither this nor any other ANDA case involving the '720 patent can be categorized as an unqualified prevail. In particular: the Osmotica ANDA case has been dismissed. The Lupin ANDA case has been stayed pending Lupin's resubmission to the FDA. In the Zydus ANDA case, the District Court of Delaware found non-infringement, affirmed by the Federal Circuit. The Watson ANDA case had two separate appeals to the Federal Circuit, each on the meaning of a different claim term, and both of which were finally determined as non-infringement. In the Mylan ANDA case, the Federal Circuit affirmed the District Court's finding of non-infringement.

Not only have plaintiffs' lawsuits meant all six ANDA applicants have had to navigate infringement challenges but also that all applicants, including defendants Amneal, have had difficulty gaining approval from the FDA for their proposed Lialda® generics. Only Zydus and Watson have gotten FDA approval and launched generic products, and these only within the last year. Defendants' s own regulatory struggles include receipt, on 16 September 2016, of an FDA rejection for genotoxic impurities in the active pharmaceutical ingredient of its generic product, and continued failure to obtain FDA approval to date. Summarizing these ANDA cases, it can be seen that plaintiffs' suits for Lialda® infringement are more Sisyphean, while defendants' efforts to get approved generics more Herculean.

In response to the complaint, defendants sought a declaratory judgment of non-infringement of its ANDA product as well as a determination of invalidity of the '720 patent claims. During a discovery period marked by at least 8 amended scheduling orders and scheduling conferences in the 16 months between September 2016 and January 2018 and several discovery disputes, plaintiffs served opening expert reports on 31 August 2017, with expert depositions taking place over the fall of 2017. On 19 January 2018, this Court held the pretrial conference.

As background to this suit's procedure, in the spring of 2017, the Zydus generic product, previously adjudicated non-infringing, entered the market, whereas by spring of 2018, the Watson generic products, also adjudicated non-infringing, entered as well. Further, in April 2018, the Federal Circuit affirmed a finding of non-infringement for Mylan's proposed generic. Between spring 2017 and April 2018, plaintiffs faced both Federal Circuit judgments of non-infringement of its '720 patent and entry of generic products in competition to Lialda®, which may have eroded its expectations of relying on the '720 patent for marketplace exclusivity.

On 3 May 2018, at Shire's initiative, the parties settled this ANDA suit by voluntarily dismissing both the infringement claims and invalidity counterclaims with prejudice. On 7 Jun 2018, Amneal filed this motion seeking a declaration this case is exceptional and $83,994 in attorneys' fees from 31 August 2017 to the date of dismissal.

Parties' Contentions

Defendants' core contention is, even though the Federal Circuit has rejected Shire's infringement theory on five separate occasions in three of the other ANDA cases, plaintiffs continued to advance that very theory in this case when it served its expert reports on 31 August 2017. Defendants further asserts that plaintiffs' infringement theory is the distribution of an excipient in its claimed pharmaceutical composition and titles this the "excipient distribution theory". (ECF Doc.373:3-4). Defendants state the '720 patent claims do not recite an excipient distributed throughout the composition, as plaintiffs advance, but rather a composition having two macroscopically separate elements: an inner lipophilic matrix and an outer hydrophilic matrix. Defendants assert the Federal Circuit made clear that an accused, generic composition can infringe the '720 claims only if it has both recited structures and that infringement cannot occur if the accused composition lacks these.

Defendants further contend plaintiffs knew their infringement theory was untenable when, on 31 August 2017, plaintiffs filed in this case its expert reports that advanced the excipient distribution theory (ECF Doc.373:1), but nonetheless pressed forward with an infringement argument it knew it couldn't win. (ECF Doc. 373-9-10). Defendants argue such action is unconscionable in that it unnecessarily delayed adjudication of a meritless case and needlessly racheted up its attorneys' fees, thereby abusing the Hatch-Waxman litigation regime and justifying a declaration of "exceptional" here. (ECF Doc.373: 16-19).

Plaintiffs contend defendant can prevail on this motion only if it shows plaintiff's infringement position was meritless as of 31 August 2017, the date when plaintiffs filed expert reports. Plaintiffs also contend defendant's labelling of plaintiffs' infringement position as the "excipient distribution theory" is incorrect, and that such mislabeling grounds a serious misrepresentation of the Federal Circuit's decisions in the other ANDA cases. Further, defendants are also incorrect in their interpretation of these Federal Circuit decisions because none opined on an "excipient distribution" infringement theory.

In addition, both parties accuse each other of unwarranted litigation-delaying tactics (ECF Doc. 373:11-13; ECF Doc. 380:5-6), which could ground a finding of the other's unreasonable litigation conduct.

3.0 Legal Standards

To award attorneys' fees in a patent infringement matter, a court must ascertain which is the prevailing party and whether the case is exceptional, as mandated by 35 U.S.C. § 285. *Octane Fitness LLC v Icon Health & Fitness, Inc.*, 134 S.Ct. 1749, 1756 (2014).

3.1 Prevailing party

The Supreme Court has defined "prevailing party" in a series of decisions involving fee-shifting statutes other than35 U.S.C. §285, stating "prevailing party" is a term of art (*Buckhannon Bd. & Care Home, Inc. v. W. Virginia Dep't of Health & Human Res.*, 532 U.S. 598, 603 (2001)) and ultimately finding that, even

nominal relief counts, so long as one party is directly benefitted by judgement or settlement.[3]

Since the Supreme Court has not defined this term in a 35 U.S.C. §285 matter, this Court looks to the Federal Circuit's interpretation, which relies on and refines the Supreme Court's: A "prevailing party" under §285 "must receive at least some relief on the merits, which alters … the legal relationship of the parties" (*Inland Steel Co. v. LTV Steel Co.,* 364 F.3d 1318, 1320 (Fed.Cir.2004) [citations omitted]) or success on a jurisdictional issue. *See Raniere v. Microsoft Corp.*, 887 F.3d 1298, 1304 (Fed.Cir. 2018) [*citing CRST Van Expedited, Inc. v. E.E.O.C.*, 136 S.Ct. 1642 (2016) for the Supreme Court's proposition that change in the parties' legal relationship must be marked by "legal imprimatur." *Buckhannon*, 532 at 604-605.]

3.2 Exceptional

Recently, the Supreme Court made clear that an exceptional case "stands out from others" in terms of the substantive strength of a party's litigating position or the unreasonable manner in which the case was litigated. *Octane Fitness,* 134 S.Ct. at 1756. An "exceptional" determination depends not on a court's application of a precise rule or formula but on the court's discretion in considering the totality of the circumstances of the individual case. *Id.* Important factors include "frivolousness, motivation, objective unreasonableness … and the need in particular circumstances to advance considerations of compensation and deterrence." *Id.* at 1756 n.6 *citing Fogerty v. Fantasy, Inc.*, 510 U.S. 517, n. 19 (1994). The moving party shows entitlement to an exceptionality award of attorneys' fees by a preponderance of the evidence. *Octane*, 134 S.Ct. at 1758.

In deciding whether a case is exceptional, this Court has primarily taken account of two considerations. The first of which is the strength of the plaintiff's litigation position--that is, the objective unreasonableness of plaintiffs' infringement theory--(*Lugus IP, LLC. V. Volvo Car Corp*, No. 12-2906, 2015 WL1399175, at *4-5 (D.N.J.26 March 2016); *Roxane Laboratories, Inc. v. Camber Pharmaceuticals, Inc. et al.*, No. 14-4042, 2017 WL 1356324 (D.N.J. 12 April 2017)). Moreover, the Federal Circuit has made clear that the focus on the party's litigation position is not the correctness or eventual success of that position, but on its substance, that is whether the position has some reasonable basis. *SFA Systems, LLC v. Newegg Inc.*, 793 F.3d 1344, 1348 (Fed. Cir. 2015) [*relying* on *Octane Fitness* to state a party's position on issues of law ultimately need not be correct for these to

[3] In an attorney fee shifting case under 42 U.S.C. §1988, the Supreme Court found" prevailing party" to be the one succeeding on any significant issue in litigation that achieves some of the benefit the party sought in bringing suit. *Hensley v. Eckerhart*, 461 U.S. 424, 433, (1983). The Court refined this both by acknowledging relief need not be judicially decreed to justify a fee award and by emphasizing there must be a settling of the dispute or some relief that affects the parties' behavior. *See Hewitt v. Helms,* 482 U.S. 755, 761, 107 S.Ct. 2672, 96 L.Ed.2d 654 (1987); *Farrar v. Hobby,* 506 U.S. 103, 111 (1992). The prevailing party inquiry centers on the material alteration of the legal relationship of the parties (*Id.*) and that relief, regardless of kind or quantum, even if nominal, must directly benefit the party at the time of judgment or settlement. *Lefemine v. Wideman*, 133S.Ct. 9, 10 (2012); *see Buckhannon,* 532 U.S. at 604, 121 S.Ct. 1835, [*citing Farrar* that a party must receive at least some relief on the merits of the claim before he/she can be said to prevail].

not stand out or be found reasonable].

In determining exceptionality, this Court has also considered whether plaintiffs' litigation conduct was unreasonable. *Iottie, Inc. et al. v. Merkury Innovations*, No. 2:15-cv-6597, 2018 WL 3425732, at *2 (D.N.J.16 July 2018); G*arfum.com Corporation v. Reflections by Ruth d/b/a Bytephoto.com* ["*Garfum II*"], No. 14-5919, 2016 WL 7325467 at *2 (16 December 2016)) [*overruling Garfum.com Corporation v. Reflections by Ruth d/b/a Bytephoto.com* ["*Garfum I*"], No. 14-5919, 2016 WL 1242762 (30 March 2016)]. For a recent exceptionality determination in this Circuit on both considerations, *see also, Green Mountain Glass, LLC v. Saint-Gobain Containers, Inc.*, 300 F.Supp. 3d 610 (D. Del. 2018).

4.0 Discussion

4.1 Jurisdiction

As a practical matter, this Court confirms its jurisdiction under the U.S. patent statute to decide the motion even though the parties' dismissal of the infringement action did not expressly retain this Court's continuing jurisdiction over subsequent matters related to the litigation.

In a situation akin to here, the Federal Circuit elucidated that a district court retains jurisdiction over a motion for attorneys' fees in a case terminated by the parties' dismissal with prejudice under Fed. R. Civ. P. 41(a)(2) because the post-dismissal motion was filed under 35 U.S.C.§ 285 of the U.S. patent statute. *Highway Equipment Company, Inc. v. Feco, Ltd.et al.*, 469 F.3d 1027, 1032-1033 (Fed. Cir. 2006). The Federal Circuit also ruled that a dismissal with prejudice under Fed. R. Civ. P. 41(a)(2) does indeed bear sufficient judicial imprimatur to effect a judicially-sanctioned change in the legal relationship of the parties as required by *Buckhannon. Id.* at 1035. Therefore, under Federal Circuit precedent, this Court exercises proper jurisdiction over the motion.

4.2 Prevailing Party Determination

On 3 May 2018, plaintiffs submitted a unilateral "Stipulation of Non-Infringement and Request for Entry of Final Judgement and Dismissal with Prejudice" under Fed. R. Civ. P. 41(a)(2). The next day, defendants filed their consent to the stipulation. On 8 May 2018, this Court unambiguously ordered final judgment of non-infringement be entered in favor of defendants and the action be dismissed with prejudice. According to *Buckhannon* and reinforced by *Highway Equipment,* this Court's order changed the parties' legal relationship and gave relief to defendants, which are determined the prevailing party here under 35 U.S.C. §285.

4.3 Exceptional Determination

4.3.1 Strength of Plaintiff's Litigation Position: Degree of Objectively Unreasonable Infringement Theory

This Court in *Lugus,* 2015 WL 13999175 at **4-5 confirmed that the strength of plaintiff's infringement position will be considered objectively unreasonable at least when the accused product cannot possibly infringe. Defendants marshal a *Lugus*-based argument; they assert plaintiffs knew the litigation position advanced in their expert reports was objectively unreasonable because of two previous Federal Circuit rulings on the '720 patent claims, which vitiated any "excipient distribution" theory. Defendants argue the Federal Circuit reversed on two separate occasions District Court findings that plaintiffs' "excipient distribution" theory of infringement was correct (S*ee Shire Development, LLC, et al. v. Watson Pharmaceuticals, Inc. et al.*, 787 F.3d 1359 (2014) ["Watson I"]); and *Shire Development, LLC, et al. v. Watson Pharmaceuticals, Inc. et al.*, 848 F.3d 981 (2017) ["Watson II"]).

In *Watson I*, the Federal Circuit, on remand from the Supreme Court, again reversed the district court's finding of infringement because the district court had adopted an incorrect claim construction. *Watson I*, 787 F.3d at 1365. The Federal Circuit construed the '720 patent claims to require two distinct matrices having a defined spatial relationship to each other: the inner lipophilic[4] matrix is separate from and inside the outer hydrophilic one (also called extra-granular space). *Watson I,* 787 F.3d at 1365-66. Also, the entire inner matrix must be lipophilic and composed entirely of lipophilic substances and likewise the entire outer matrix must be hydrophilic and composed entirely of hydrophilic substances. *Id.* This contrasted with the district court's construction that the active ingredient, mesalamine, was dispersed in both lipophilic and hydrophilic matrices because mesalamine was in both granules and spaces outside the granules. *Id*. at 1364. Thus, the *Watson I* court required the recited composition to have a much more distinctive architecture, primarily because of the court's review of the claim language itself, of the effect of the prosecution history and of the specification. *Id.* at 1366-1367.

In *Watson II*, the Federal Circuit interpreted the recited transition term "consisting of" to mean that each matrix in the '720 patent can contain only those substances listed in the recited Markush grouping. In particular, the lipophilic matrix was recited to have only lipophilic substances; and the hydrophilic matrix to have only lipophilic substances. Thus, the "consisting of" term dictated the recited composition of the inner and the outer matrix. Because of this, the Court found that, by containing a strongly lipophilic substance, magnesium stearate, in the extra-granular space (hydrophilic matrix), Watson's product necessarily avoided infringement. By implication, *Watson II* reinforced the *Watson I* distinct architecture of the recited composition described above.

Defendants assert plaintiffs' "excipient distribution" theory of infringement is that the recited

[4] Lipophilic means the ability for substances to dissolve in fats, oils, and lipids, which tend to be non-polar; whereas hydrophilic substances dissolve in water and tend to be polar. At heart, the invention of the '720 patent literally works due to the well-known chemical mechanism that oil and water do not mix.

inner lipophilic matrix can be a distribution of magnesium stearate; and the outer hydrophilic matrix (extra-granular space) can be a distribution of sodium carboxymethylcellulose ("CMC"). They imply this "excipient distribution" theory was the only one by which defendants' product could infringe, and that the Federal Circuit ruled against that theory twice. Thus, the basis for defendant's exceptionality argument is that by pressing forward once again in the expert reports with a judicially lifeless infringement theory, plaintiffs revealed a litigation position that could only be objectively unreasonable.

This Court does not agree with defendants' arguments. Plaintiffs contend that their infringement theory in this case was not based on an "excipient distribution" theory but on the observed and tested-for presence, at least to plaintiffs' experts, that Amneal's ANDA product contained both recited matrices. ECF Doc. 380: 16-17. Plaintiffs argue that the Federal Circuit rulings in *Watson I* and *II* were not relevant here. *Id.* at 15, 18. In particular, plaintiffs argue the testing done by their experts of Amneal's product showed it had physical architecture akin to that claimed (and construed by the Federal Circuit). Specifically, Amneal's product appeared to have physical clusters, i.e., inner lipophilic matrices of magnesium stearate, that could function to control the release of mesalamine. Moreover, plaintiffs argued that such magnesium stearate clusters formed inner lipophilic matrices that appeared as "beyond just dispersed". *Id.* In other words, plaintiffs argue that the physical structure of the lipophilic matrices in defendants' product appeared as continuous but was beyond appearing as dispersed and therefore directly infringed the '720 patent claims.

The description by plaintiffs' expert Dr. Little—that the lipophilic matrix of magnesium stearate appeared as "beyond just dispersed" and made up a volume[5] (*Id*. at 17)—may not be the strongest scientific argument to counter defendants' charge that plaintiffs relied on an "excipient distribution" theory. But, plaintiffs need not set forth a strong argument to prevail in a determination of exceptional. Their argument may be a weak and nonetheless still not invoke exceptionality. *SFA Systems*, 793 F.3d at 1348; and *Garfum II*, 2016 WL 7325467 at *3.

Moreover, a "mini-trial" is not necessary here even if plaintiffs' litigation position was losing from the beginning. This is because plaintiffs' arguments and their experts' reports and tests demonstrate a belief that the degree of qualitative difference between the claimed invention and the accused product was chemically insignificant and indicated, at least to plaintiffs, infringement. *See Deckers Outdoor Corp. v. Romeo & Juliette, Inc.*, No. 15-2812, 2016 WL5842187, at *3 (C.D. Cal. 5 Oct 2016) [*recognizing* that if a party has set forth some good faith argument in favor of its position, it will not be found to have advanced exceptionally meritless claims [citations omitted]].

Ultimately, determining the substantive strength of a plaintiff's infringement position in this case is a balancing act of the differences between what plaintiffs say their infringement theory is and what defendants say plaintiffs' theory is. To defendants, plaintiffs' litigation position looked baseless as an

[5] that is, had physical structure and was not a homogeneous distribution throughout.

"excipient distribution" theory. To plaintiffs, their position was based on showing and explaining granules of magnesium stearate to constitute inner lipophilic matrices. Their position was also based on differentiating, at least in plaintiffs' view, that the infringement theory here was not the same theory as adjudicated by the Federal Circuit.

Whether plaintiffs are correct about their theory is not the issue here; after all, the correctness of their argument would have been decided at trial. Moreover, they do not have to show here that their infringement theory would have been successful at trial. Rather, what plaintiffs did have to show is that they had some theoretical and chemical back-up to support what could very well be a substantively weak infringement theory. Their scientific back-up supports a finding that their infringement position was not objectively unreasonable. In considering plaintiffs' litigation position, this Court does not find this matter exceptional under 35 U.S.C. §285.

4.3.2 Reasonableness of Plaintiffs' Litigation Conduct

The analysis turns now to the manner in which the infringement case was litigated: unreasonable conduct prompts a finding of exceptional. Defendants put forth an economic incentive theory why plaintiffs employed delaying tactics and did not settle or resolve the litigation sooner. ECF Doc. 11-13. They imply that keeping the Amneal generic tied up in infringement litigation was a rational business objective for plaintiffs as the '720 patent[6] expires in 2020, and has but a few years left to keep generating mega-million dollar revenues as other FDA-approved Lialda® generics acutely cut into these. *Id.* at 12.

Defendants cite as an example a discovery dispute from summer 2017 in which plaintiffs' requested from Magistrate Judge Schneider that defendants provide greater specificity in their status reports about FDA approval. ECF Doc. 252. The request was denied both because plaintiffs had canceled a deposition of an Amneal C-level employee, which could have resolved the dispute, and because such cancellation indicated to Magistrate Judge Schneider that what plaintiffs ultimately wanted was to get the case delayed until FDA approval of Amneal's product. ECF Doc. 268: 2. In effect, defendants conflate their argument about plaintiffs' weak litigation position into their contention of unreasonable litigation conduct. To wit, plaintiffs knew their infringement theory was untenable and should have settled earlier.

As almost every ANDA litigation case is hotly contested during discovery and in dispositive motions and represents high-stakes revenue maintenance or loss, finding unreasonable conduct during such litigation is a balancing of the totality of litigation conduct. *Green Mt. Glass*, 300 F. Supp. at 631. Bitter discovery disputes and strong economic reasons that de-incentivize settlement, even coupled to a weak infringement theory, are par for the course, and do not make this case "stand out from others". *Id*. This Court has found that "decisions granting fees after *Octane Fitness* have generally concerned egregious litigation conduct". G*arfum II*, 2016 WL 7325467, at *6. To the point, this Court does not find

[6] Currently plaintiffs' only U.S. patent covering Lialda®

egregious litigation conduct in this matter and consequently does not find exceptionality under 35 U.S.C. §285.

5.0 Conclusion

Under neither consideration--the objectively baseless litigation theory nor the unreasonable litigation conduct--does this Court find plaintiffs' behavior exceptional under 35 U.S.C. §285 after the filing date of their expert reports and denies defendants' motion to award attorney fees from that date up to settlement. An Order accompanies.

Date: 11 October 2018

s/ Robert B. Kugler
ROBERT B. KUGLER
United States District Judge